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Management of infected transvenous permanent pacemakers[1]

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Twenty-four instances of sepsis after permanent pacemaker implantations are reviewed. Sepsis involving the pacemaker generator usually developed shortly after operation (median time two and a half weeks) whereas electrode catheter infection occurred later (median time 33 weeks) after erosion of the electrode loop in the neck. Factors predisposing to sepsis were present in 12 patients. Staphylococcus aureus *and* albus *were the commonest infecting organisms. An unexplained finding was the increasing risk of generator sepsis with each subsequent replacement.*

Radical surgery, consisting of removal of the entire septic pacemaker generator plus electrode with implantation of a new generator-electrode system effected a cure in 16 of the 17 patients in whom it was employed. Antibiotic therapy with or without conservative surgery proved less successful. One patient developed septicaemia and survived, and one patient died as a result of ventricular fibrillation during a period of temporary pacing.

With increasing use of permanent pacemakers, the number of patients involved in complications of this form of treatment may be expected to increase proportionately. In patients in whom the indications for permanent pacing are not unequivocal, the case for advising pacing must be tempered by consideration of the potential complications of the procedure. One of the problems encountered is sepsis and the risk recurs with each subsequent pacemaker generator change. The medical literature contains differing policies regarding management of this important complication and it seemed timely to review local experience of this problem.

Material and methods

From 1963 until 1972, 378 permanent pacemakers were implanted in 169 patients; a total of 173 transvenous lead systems were employed, 4 of which were in patients with previous epicardial systems.

Methods of transvenous pacing

Over the 9-year period the preferred method of pacing changed from epicardial to transvenous. Epicardial systems were excluded from this analysis as no cases of sepsis were encountered. The transvenous method employed initially in 15 patients was a one-stage insertion of a transvenous electrode from the external jugular vein with the pacemaker generator buried in the axillary region. This was abandoned in 1966 in favour of a two-stage transvenous procedure with the permanent pacemaker and an indifferent electrode buried beneath the subcutaneous tissues of the lower abdominal wall

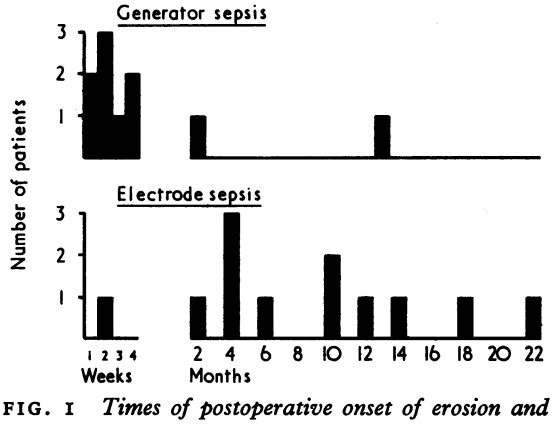

FIG. 1 *Times of postoperative onset of erosion and sepsis of pacemaker generators and transvenous electrodes.*

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TABLE I *Details of patients with septic pacemaker systems*

Case no.	*Site of sepsis*	*Time of onset of sepsis after operation*	*Where surgery performed*	*No. of pacemaker generator*	*Predisposing factors in sepsis*
1	Transvenous electrode	10 mth	Catheter lab	—	—
1	Indifferent electrode	1 mth	Another centre	—	—
1	Transvenous electrode	3 mth	Another centre	—	Electrode repositioned once
2	Transvenous electrode	14 mth	Catheter lab	—	Diabetes mellitus
2	Pacemaker generator	1 wk	Catheter lab	2	Diabetes mellitus
3	Transvenous electrode	2 mth	Operating theatre	—	—
4	Indifferent electrode	3 mth	Another centre	—	Diabetes mellitus
5	Pacemaker generator	3 wk	Catheter lab	4	Diabetes mellitus
6	Pacemaker generator	10 dy	Catheter lab	3	Septic ulcer following fractured leg
7	Transvenous electrode	10 mth	Catheter lab	—	Pneumonia 1 mth before
8	Pacemaker generator	2 wk	Operating theatre	1	—
9	Pacemaker generator	2 mth	Catheter lab	5	—
10	Transvenous electrode	14 wk	Catheter lab	—	Electrode repositioned 3 times
11	Transvenous electrode	2 wk	Catheter lab	—	Electrode repositioned once
12	Transvenous electrode	3 mth	Catheter lab	—	—
13	Pacemaker generator	1 mth	Another centre	2	—
14	Pacemaker generator	13 mth	Operating theatre	4	—
15	Pacemaker generator	1 mth	Operating theatre	1	Aspiration of postoperative haematoma
16	Transvenous electrode	6 mth	Catheter lab	—	Electrode repositioned twice
17	Pacemaker generator	2 wk	Catheter lab	3	—
18	Transvenous electrode	12 mth	Operating theatre	—	Electrode repositioned twice
19	Transvenous electrode	22 mth	Catheter lab	—	Diabetes mellitus
20	Pacemaker generator	10 dy	Operating theatre	5	—
21	Transvenous electrode	18 mth	Catheter lab	—	—

Culture result	*Conservative treatment and outcome*	*Radical surgical treatment and outcome*
Staph. aureus	Antibiotics (failed)	One-stage (successful)
Unknown	Local surgical removal of indifferent electrode (failed)	Reversed two-stage (successful)
No growth	Local surgery (failed)	One-stage (successful)
Unknown	Local surgery (successful)	—
Alkaligenes faecalis; Candida albicans; Staph. albus	Antibiotics (failed)	Removal of septic pacemaker system (successful)
Staph. albus	Antibiotics (failed)	Two-stage (successful)
Staph. aureus	Antibiotics (failed); local surgery (successful)	—
Staph. albus	Antibiotics (successful)	—
Staph. albus	Local surgery (failed)	Two-stage (patient died after first stage following ventricular fibrillation)
Staph. aureus	Antibiotics (successful)	—
No discharge	Antibiotics (successful)	—
No growth	None	Two-stage (successful)
Staph. aureus; paracolon	Antibiotics (failed); local surgery (failed)	One-stage (successful)
Staph. aureus (septicaemia)	None	Two-stage (successful)
No growth	Antibiotics (failed)	One-stage (successful)
Unknown	Antibiotics (failed)	Two-stage (successful)
No growth	None	Two-stage (successful)
Yeasts ? type; *Staph. aureus; Staph. albus;* coliforms; B-haemolytic streptococcus	Local surgery (failed)	Two-stage (successful)
No growth	Antibiotics (failed), local surgery (successful)	—
No discharge	Antibiotics (successful)	—
Staph. aureus; Staph. albus	Antibiotics (failed)	One-stage (successful)
Staph. albus	Antibiotics (failed)	One-stage (successful)
Staph. aureus	Antibiotics (failed)	Two-stage (successful)
No growth	Local surgery (successful)	—

(Gotsman *et al.*, 1966). Forty-four transvenous systems were implanted using this two-stage method. In 1968, a one-stage procedure was again adopted using the external or internal jugular vein, and in a few instances the cephalic vein. A total of 114 new transvenous systems was implanted using this one-stage procedure. General anaesthesia was almost always used for pacemaker implantations and replacements. Conventional skin preparation and a wide range of antibiotics were used routinely for all pacemaker implantations and generator changes. Over the past two years of the survey lincomycin alone was the prophylactic antibiotic of choice, but previously most patients received combinations including penicillin, streptomycin, and oxacillin.

Pacemaker replacements and one-stage transvenous pacemaker implants were initially done in the operating theatre using a portable image intensifier. After 1969, transvenous pacemaker implantations and pacemaker replacements were usually done in the catheter laboratory. A total of 105 one-stage transvenous implantations and 93 generator replacements were performed in the catheter laboratory.

Results

Incidence and time of infection

Sepsis, defined by the development of redness, tenderness, and swelling, with or without necrosis of the skin overlying any part of the pacemaker system, developed in 20 instances among the 378 pacemaker operations (5·3%), and another 4 patients with sepsis who had been operated upon elsewhere were referred for treatment. Thus, 24 instances of sepsis were observed in 21 patients, as one patient developed sepsis on 3 occasions while another patient had sepsis twice (Table 1). Among the local 20 cases sepsis in the generator site occurred in 9 patients and sepsis of the electrode in the neck in 11 patients. Of the 4 referred cases one had a septic generator site, one a septic transvenous electrode, and 2 had sepsis related to the subcutaneous indifferent electrode (Table 1).

Of the 378 locally operated cases, 10 (2·6%) and all 4 of the referred cases developed evidence of sepsis within 4 months of operation. Among patients with pacemaker generator sepsis the median time of onset of infection postoperatively was 2½ weeks, with a range of 1 to 56 weeks (Fig. 1). Patients with infected transvenous electrodes showed a very different peak time of sepsis developing, with a median time of 33 weeks and a range of 2 to 95 weeks (Fig. 1).

Causes predisposing to sepsis

Of the locally operated patients who developed sepsis, 14 had undergone surgery in the catheterization laboratory and 6 had been operated upon in theatre. Details of the operating theatre facilities of the 4 referred cases were not known. If one arbitrarily regards sepsis occurring within 4 months

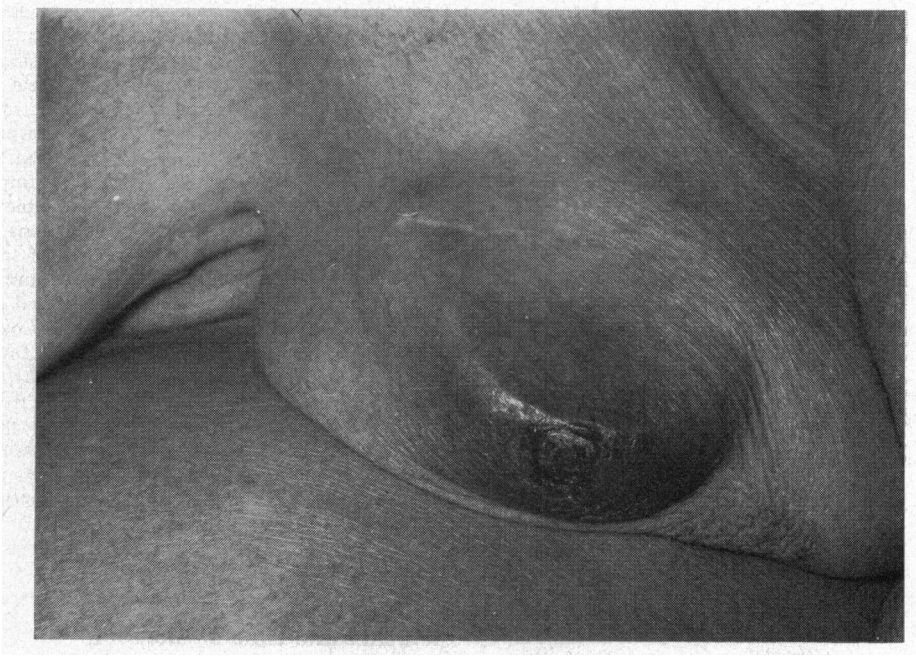

FIG. 2 *Erosion and early sepsis of pacemaker generator which has been implanted too superficially.*

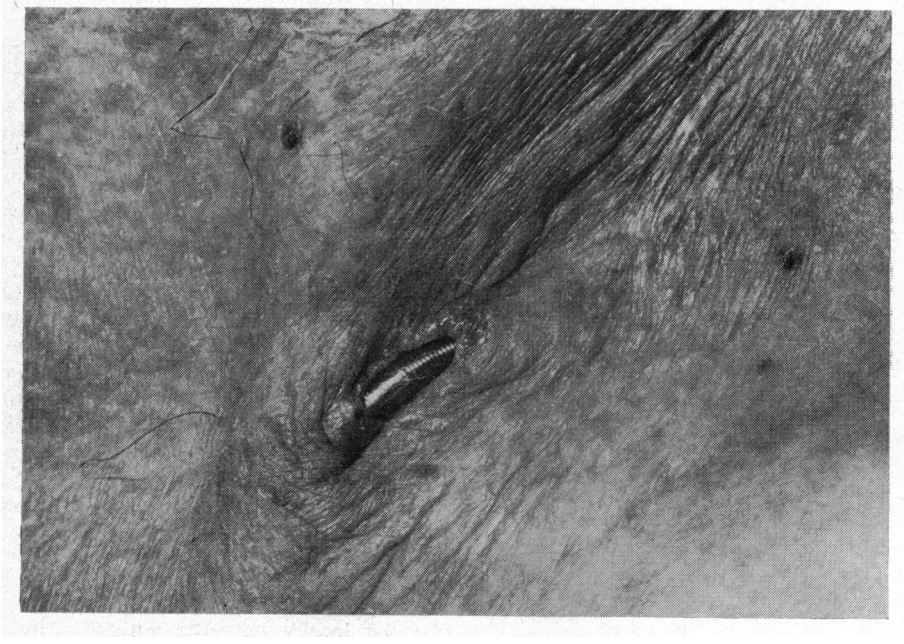

FIG. 3 *Erosion of tranvenous electrode in the neck adjacent to where it enters the external jugular vein.*

of operation as being a surgical complication, then 7 of 198 cases operated upon in the catheterization laboratory developed sepsis (3·5%), and 4 of the 180 cases operated upon in the theatre developed sepsis (2·2%).

In 12 of the 21 patients possible predisposing causes of sepsis were present. Five instances of sepsis occurred in 4 patients with diabetes mellitus. Sepsis occurred between 2 weeks and 1 year after remanipulation of the electrode in 5 patients. Sepsis followed aspiration of a haematoma of the generator pocket in 1 patient on anticoagulants. Two patients developed sepsis after a septic traumatic leg ulcer in one and pneumonia in another. No difference in the incidence of sepsis was found in patients whose pacemaker wounds had been drained compared with those in whom no drain had been inserted at the time of operation.

The 10 patients with infected pacemaker generators represented 2 of 195 first pacemaker implants (1·0%), 2 of 96 second pacemaker implants (2·0%), and 6 of 108 instances in which a third or subsequent pacemaker had been implanted (6·0%). The difference between the sepsis rates of first and third or subsequent generator implants was statistically significant ($P = 0{\cdot}003$) (Armitage, 1971).

The method of pacing appeared to influence the site of sepsis. Among the 15 early one-stage transvenous cases sepsis developed in 2, involving the electrode in the neck in both cases. Sepsis was seen in 8 of the 44 patients operated upon subsequently using the two-stage transvenous procedure: 6 of these infections complicated pacemaker generator replacements. In contrast, there were 10 infections among the 114 patients with the later one-stage transvenous pacing system, and 8 of these involved erosion and infection of the transvenous electrode in the neck.

Bacteriology

Coagulase positive *Staphylococcus aureus* was cultured from the infected site in 8 instances and coagulase negative *Staphylococcus albus* in 7 (Table 1). Yeasts were isolated in two patients and coliforms, paracolon, *Alkaligenes faecalis*, and beta-haemolytic streptococcus on one culture each. More than one organism was grown from one or more pus swabs from many of the patients. Pus swab culture was negative in 6 patients, in 3 of whom the primary problem was one of necrosis of the pacemaker generator or electrode through an inadequate overlying skin layer with clinical signs of secondary infection. The other 3 patients had been on antibiotics before pus swabs were taken. *Staphylococcus aureus* was cultured from the blood in a single patient who had clinical evidence of septicaemia associated with sepsis.

Treatment

Table 2 lists the types of medical and/or surgical treatment employed and their success rates. Conservative medical treatment consisted of combinations of two or more of the following antibiotics: penicillin, streptomycin, oxacillin, cephalothin, and albamycin T (novobiocin plus tetracycline). Conservative surgical treatment consisted of local débridement and reimplantation of the electrode or generator with a more substantial overlying tissue layer. In one patient (Case 15), with a septic abdominal generator pocket, it consisted of exposing the electrode over the chest wall and connecting it to a new generator in the pectoral region while the old generator site was ablated.

Two-stage radical surgery comprised insertion of a temporary pacemaker, removal of the entire septic pacemaker electrode system, and implantation of a completely new pacemaker system at a second operation one or two weeks later once the wounds had healed. Reversed two-stage radical surgery reversed the process with initial implantation of a new system and removal of the septic system at a second operation. Radical one-stage surgery consisted of implantation of the new pacemaker system and removal of the septic system at a single operation. All forms of surgical treatment were covered with antibiotic therapy as listed above and where a new pacemaker system was necessary it was routinely implanted on the side of the body opposite to that where sepsis had occurred. The single patient (Case 2) who had his septic pacemaker system removed without subsequent pacing has been managed on medical treatment alone.

Staphylococcus aureus septicaemia developed in one patient (Case 11) after removal of the septic transvenous pacemaker. After prolonged antibiotic therapy a new epicardial pacemaker system was uneventfully implanted. One patient (Case 6) died as an indirect result of pacemaker sepsis and is the only exception among the patients successfully treated by radical surgery. During temporary pacing after removal of his septic pacemaker system he developed ventricular fibrillation and died the day after resuscitation. Necropsy showed a small haematoma in the right ventricular apex, thought to have been due to penetration of the myocardium by the temporary electrode. Electrocution resulting from an induced current gaining access to the heart via the electrode could not be excluded however.

TABLE 2 *Results of treatment of patients with septic pacemaker systems*

	Successful conservative medical treatment	*Successful conservative surgical treatment*	*Successful two-stage radical surgery*	*Successful one-stage radical surgery*	*Successful reversed two-stage radical surgery*	*Surgical removal of septic pacemaker system*
Infected pacemaker generator	3/6	0/2	5/6	—	—	1/1
Infected transvenous electrode	1/8	3/5	2/2	6/6	—	—
Infected indifferent electrode	0/1	1/2	—	—	1/1	—
Total	4/15	4/9	7/8	6/6	1/1	1/1

Discussion

Review of 21 of the largest series of permanent implanted pacemakers (Van Dijk, 1964; Davies and Siddons, 1965; Harris *et al.*, 1965; Center, Castillo, and Keller, 1967; Donmoyer, DeSanctis, and Austen, 1967; Lagergren, 1967; Bigelow *et al.*, 1968; Firor *et al.*, 1968; Gadboys, Lukban, and Litwak, 1968; Edhag and Lagergren, 1969; Frank, Zoll, and Linenthal, 1969; Lopez-Bescos and Deuchar, 1969; Torresani *et al.*, 1969; Goldstein *et al.*, 1970; Parsonnet, 1970; Siggers and Deuchar, 1970; Bernstein, Rotem, and Peretz, 1971; Dargan and Norman, 1971; Querimit, Klatt, and Kroncke, 1971; Green *et al.*, 1972; Linschoten *et al.*, 1973) revealed an overall sepsis rate of 197 in 3639 operations (5·4%). The frequency of sepsis varied from zero (Bigelow *et al.*, 1968) to 41 per cent (Harris *et al.*, 1965). Like certain other workers at that time (Van Dijk, 1964; Lopez-Bescos and Deuchar, 1969; Zoll *et al.*, 1961), however, the group with the highest sepsis rate was having problems with tissue reactions to the generator capsule and sepsis followed effusion and fistula formation, causing a sepsis rate far above currently acceptable levels. The highest observed sepsis rates since these early days have been reported by Firor and colleagues (1968), with 12 cases in 96 operations (12·6%) and Edhag and Lagergren (1969) with 32 cases among 260 (12·3%).

The median times of appearance of sepsis of pacemaker generators and electrodes in this series reveal that generator sepsis usually presented early, whereas septic electrodes presented later. It seems likely, therefore, that generator sepsis is usually related to infection introduced at the time of operation, whereas sepsis later on may have a different aetiology. Blood-borne infection (Firor *et al.*, 1968; Siddons and Sowton, 1967) and diabetes (Torresani *et al.*, 1969) have been invoked, but poor surgical technique appears the likeliest explanation for late sepsis complicating erosion of the generator (Fig. 2) or electrode (Fig. 3) which has been implanted too superficially (Harris *et al.*, 1965; Lagergren, 1967; Edhag and Lagergren, 1969; Torresani *et al.*, 1969; Goldstein *et al.*, 1970; Furman and Escher, 1970). Poor siting of the electrode loop in the neck often complicates its remanipulation necessitated by migration of the tip.

In this hospital the majority of pacemakers continue to be implanted in the catheterization laboratory because of the shortage of operating theatre time, despite the slightly increased risk of infection found in this and in other series (Firor *et al.*, 1968; Torresani *et al.*, 1969).

Although haematoma formation in the generator pocket can lead to secondary infection (Parsonnet, 1970; Grendahl *et al.*, 1969), as found in one of our cases (Case 15), drainage of the wound did not influence the sepsis rate in this series. Re-exploration of the generator pocket for any reason is known to predispose to sepsis (Dargan and Norman, 1971; Green *et al.*, 1972; Nanson *et al.*, 1967). Re-exploration for replacement of the pacemaker generator at any stage after its original implantation appears to carry with it an ever increasing risk of sepsis with consecutive operations as was shown in this series. Parsonnet (1970) made the same observation independently, finding that only 10 per cent of pacemaker extrusions occurred after the first operation and 90 per cent followed subsequent operations. The explanation for this phenomenon is unknown at present.

The higher sepsis rate among patients with the two-stage transvenous system was unexplained and occurred most commonly at the time of generator replacement. Though the implantation area is possibly more difficult to sterilize effectively than the upper trunk, this does not explain why the

original generator implants were not similarly susceptible to infection.

Although conservative medical treatment succeeded where local signs of infection existed without necrosis of overlying tissues, it was ineffective once ulceration of the electrode or pacemaker had occurred (Table 2). Conservative surgical treatment in combination with antibiotics failed where it was the pacemaker generator which had ulcerated and become infected (Table 2). More recently, successful conservative methods of treatment of ulcerating septic pacemaker generators have included re-exploration of the wound with neomycin irrigation plus prolonged antibiotics (Furman and Escher, 1970), local wound débridement and antibiotic irrigation of the generator pocket with or without systemic antibiotics (Dargan and Norman, 1971; Furman *et al.*, 1972), and immersion in glutaraldehyde followed by washing of the generator before reimplantation (Green *et al.*, 1972).

Most authors favour radical surgery once the electrode and/or pacemaker generator has ulcerated through the skin (Davies and Siddons, 1965; Firor *et al.*, 1968; Torresani *et al.*, 1969; Smyth, 1969; Thalen *et al.*, 1969). Two-stage radical surgery with its potentially hazardous period of temporary pacing between operations has the disadvantage of requiring two operations. Sepsis localized to a small area in the neck was successfully treated by a single operation in every case (Table 2). Implantation of a new pacemaker system with subsequent removal of the septic system at a second operation is no longer recommended as it carries the risk of sepsis developing in the new pacemaker system. The single successfully treated instance of septicaemia in this series is less than the rate reported with septic permanent pacemakers by other authors (Firor *et al.*, 1968; Edhag and Lagergren, 1969; Torresani *et al.*, 1969). The present series suggests that treatment should be directed at the staphylococcus initially as it was the most frequently found infective organism (Table 1).

In the light of this and other reported series, it is recommended that pacemakers should be implanted in an operating theatre with fixed image intensification equipment wherever possible; that both generator and electrode should have a generous overlying layer of tissue, and that prophylactic antistaphylococcal antibiotics should be used to cover all operations. Subsequent intercurrent infections should be treated with antibiotics to reduce the risk of secondary infection of the pacemaker site.

Before erosion of an infected pacemaker generator or electrode, antibiotics other than those used prophylactically at the time of operation and appropriate to the treatment of resistant *Staphylococcus aureus* or *albus* should be used. Surgical repositioning of the electrode loop at a deeper site in the neck plus débridement of all granulation tissue, with antibiotic cover, is advised for the eroded pacemaker electrode loop. Where conservative surgery fails a new pacemaker system should be implanted on the opposite side of the body and the old septic system should be removed by a separate operator at the same operation.

Where erosion of the pacemaker generator has occurred there may be a place for re-exploration, débridement, and irrigation of the generator pocket with antibiotic solutions, as has recently been proposed. The alternative, more radical approach used in this series consists of surgical removal of the entire septic pacemaker system under antibiotic cover, using temporary transvenous pacing until a new pacemaker system is implanted on the opposite side of the body, once all wounds have healed and there is no longer evidence of infection present. The above recommendation is aimed to avoid unnecessary surgery when conservative methods may succeed and reduce surgical interference to a minimum.

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